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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,417	02/05/2004	Takuya Watanabe	2004_0003	2869

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,417	WATANABE ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 7-9, and 17-18, drawn to an isolated polynucleotide which contains a base sequence 95% homologous to SEQ ID NO: 2, classified in class 536, subclass 23.5.

II. Claims 1-4, 7-9, and 17-18, drawn to an isolated polynucleotide which contains a base sequence 95% homologous to SEQ ID NO: 6, classified in class 536, subclass 23.5.

III. Claims 5-6 and 12-14, drawn to the antisense polynucleotide of SEQ ID NO: 2, classified in class 536, subclass 23.1.

IV. Claims 5-6 and 12-14, drawn to the antisense polynucleotide of SEQ ID NO: 6, classified in class 536, subclass 23.1.

V. Claim 10, drawn to a method for diagnosis of diseases comprising using the polynucleotide of SEQ ID NO: 2, classified in class 435, subclass 6.

VI. Claim 10, drawn to a method for diagnosis of diseases comprising using the polynucleotide of SEQ ID NO: 6, classified in class 435, subclass 6.

VII. Claim 11, drawn to a method for treatment of diseases comprising using the polynucleotide of SEQ ID NO: 2, classified in class 514, subclass 44.

VIII. Claim 11, drawn to a method for treatment of diseases comprising using the polynucleotide of SEQ ID NO: 6, classified in class 514, subclass 44.

IX. Claim 15, drawn to a method for diagnosis of diseases comprising using the antisense of the nucleic acid sequence of SEQ ID NO: 2, class 435, subclass 6.

X. Claim 15, drawn to a method for diagnosis of diseases comprising using the antisense of the nucleic acid sequence of SEQ ID NO: 6, classified in class 435, subclass 6.

XI. Claim 16, drawn to a method for treatment of diseases comprising using the antisense of the nucleic acid sequence of SEQ ID NO: 2, classified in class 514, subclass 44.

XII. Claim 16, drawn to a method for treatment of diseases comprising using the antisense of the nucleic acid sequence of SEQ ID NO: 6, classified in class 514, subclass 44.

XIII. Claim 19, drawn to a method for screening a compound that alters the binding property between a ligand and a protein comprising using the protein encoded by the polynucleotide of SEQ ID NO: 2, classified in class 435, subclass 7.1.

XIV. Claim 19, drawn to a method for screening a compound that alters the binding property between a ligand and a protein comprising using the protein encoded by the polynucleotide of SEQ ID NO: 6, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Each of SEQ ID NOs: 2 and 6 is a unique nucleic acid sequence, requiring a unique search of the prior art. Furthermore, the antisense sequences of SEQ ID NOs: 2 and 6 are unique nucleic acid sequences. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

b. Inventions V-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions V-XIV are different methods because they require different ingredients, process steps, and endpoints. Groups V-XIV are different methods requiring different method steps, wherein each is not required, one for another. For example, Group V requires search and consideration of diagnosis of diseases utilizing the polynucleotide of SEQ ID NO: 2, which is not required by the other

inventions. Group VI requires search and consideration of diagnosis of diseases utilizing the polynucleotide of SEQ ID NO: 6, which is not required by the other inventions. Group VII requires search and consideration of efficacy of therapy of administration of the polynucleotide of SEQ ID NO: 2, which is not required by the other inventions. Group VIII requires search and consideration of efficacy of therapy of administration of the polynucleotide of SEQ ID NO: 6, which is not required by the other inventions. Group IX requires search and consideration of diagnosis of diseases utilizing the antisense of the polynucleotide of SEQ ID NO: 2, which is not required by the other inventions. Group X requires search and consideration of diagnosis of diseases utilizing the antisense of the polynucleotide of SEQ ID NO: 6, which is not required by the other inventions. Group XI requires search and consideration of efficacy of therapy of administration of the antisense of the polynucleotide of SEQ ID NO: 2, which is not required by the other inventions. Group XII requires search and consideration of efficacy of therapy of administration of the antisense of the polynucleotide of SEQ ID NO: 6, which is not required by the other inventions. Group XIII requires search and consideration of screening a compound that alters the binding property between a ligand and a protein comprising using the protein encoded by the polynucleotide of SEQ ID NO: 2, which is not required by the other inventions. Group XIV requires search and consideration of screening a compound that alters the binding property between a ligand and a protein comprising using the protein encoded by the polynucleotide of SEQ ID NO: 6, which is not required by the other inventions. Therefore, each method is divergent in materials and steps. For these reasons the Inventions X-XIV are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups V-XIV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups V-XIV together.

c. Inventions I and V, VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed polynucleotide can be used in materially different methods, such as to generate proteins or as a probe in nucleic acid hybridization assays.
Searching the inventions of Groups I and V, VII together would impose serious search burden. The inventions of Groups I and V, VII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotide of SEQ ID NO: 2 and the methods of diagnosis and treatment are not coextensive.

d. Inventions II and VI, VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed polynucleotide can be used in materially different methods, such as to generate proteins or as a probe in nucleic acid hybridization assays.
Searching the inventions of Groups II and VI, VIII together would impose serious search burden. The inventions of Groups II and VI, VIII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotide of SEQ ID NO: 6 and the methods of diagnosis and treatment are not coextensive.

e. Inventions III and IX, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed polynucleotide can be used in materially different methods, such as to generate antisense peptides or in *in vitro* cell assays. Searching the inventions of Groups III and IX, XI together would impose serious search burden. The inventions of Groups III and IX, XI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antisense of the polynucleotide of SEQ ID NO: 2 and the methods of diagnosis and treatment are not coextensive.

f. Inventions IV and X, XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the claimed polynucleotide can be used in materially different methods, such as to generate antisense peptides or in *in vitro* cell assays. Searching the inventions of Groups IV and X, XII together would impose serious search burden. The inventions of Groups IV and X, XII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antisense of the polynucleotide of SEQ ID NO: 6 and the methods of diagnosis and treatment are not coextensive.

g. Inventions I and VI/VIII-XIV are unrelated because the product of Group I is not used or otherwise involved in the processes of Groups V/VIII-XIV.

h. Inventions II and V/VII/IX-XIV are unrelated because the product of Group II is not used or otherwise involved in the processes of Groups V/VII/IX-XIV.

g. Inventions III and V-VIII/X/XII-XIV are unrelated because the product of Group III is not used or otherwise involved in the processes of Groups V-VIII/X/XII-XIV.

g. Inventions IV and V-IX/XI/XIII-XIV are unrelated because the product of Group IV is not used or otherwise involved in the processes of Groups V-IX/XI/XIII-XIV.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
09 January 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER